M 20460

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

July 8, 1998

WARNING LETTER
CHI-29-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Paul McQuade, Vice President
Doctors Park Network
Doctors Park West Location
2524 Farragut
Springfield, IL 62704

Dear Mr. McQuade:

Your mammography facility (MQSA certificate #137737) was inspected on June 4, 1998, by a representative of the State of Illinois, acting on behalf of the Food and Drug Administration (FDA). This inspection was closed on June 22, 1998, after your facility failed to respond to the inspector's repeated requests for additional personnel documentation. The inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Section 900.12.

The deficiency noted below appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was mailed to you by the State of Illinois.

Level 1

Your site lacked the required documentation to show that an interpreting physician, Dr. [redacted] was either certified by an approved board or that he had received two months of full-time training in the interpretation of mammograms.

It is the responsibility of each mammography facility to obtain proper documentation of personnel qualifications prior to allowing individuals to perform or interpret mammograms at that facility. The FDA expects that all personnel records will be available at the time of inspection for review. As stated earlier, despite being given an opportunity to supply the missing documentation to the inspector following the close of the inspection, your site submitted none. Consequently, your facility has been cited with the above deficiency.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and the FDA regulations. You are responsible for investigating and determining how the deficiency was allowed to occur and for promptly initiating permanent corrective actions.

Because this deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography provided by your facility, it represents a violation of the law and may result in the FDA taking regulatory action without further notice to you. These regulatory actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to comply with, the MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography activity.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than the FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

It is necessary for you to act on this matter immediately. Within 15 working days after receiving this letter, you should notify the FDA in writing of:

the specific steps you have taken to **correct** the above-mentioned violation;

each step your facility is taking to **prevent the recurrence** of similar violations.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

Lynn E. Jenkins
Regional Radiological Health Representative
Central Region-Chicago
Food and Drug Administration
Suite 510
20 North Michigan Avenue
Chicago, IL 60602

Also, send a copy to:

Donald Agnew, Health Physicist
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Lynn Jenkins at (312) 353-9400, x29.

Sincerely,

\s\
Raymond V. Mlecko
District Director
Chicago District Office

cc: Donald Agnew, Health Physicist
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
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American College of Radiology
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